

REMARKS

Claims 7-14 are pending in the Application and will remain pending after entry of this Response. Applicant submits herewith a Declaration of Anthony P. Shuber Under 37 C.F.R. § 1.132 and a Terminal Disclaimer.

Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

Claims 7-14 were considered and stand rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Patent Office alleges that the specification does not enable the scope of the claims. In response to the rejection, Applicant submits the attached Declaration. The Declaration is executed by the inventor, Anthony P. Shuber, and the data reported in the Declaration support Applicant's contention that the specification of the instant application enables claims 7-14.

For example, at page 11, lines 8-29 and page 12, lines 1-7 of the specification, Applicant teaches methods "useful to detect nucleic acid indicia of cancer or precancer in any tissue or body fluid sample." Additionally, for example, at page 12, lines 8-18 of the specification, Applicant teaches that "[t]he invention takes advantage of the recognition that large fragments exist in greater abundance in abnormal samples than in normal samples" and that "the precise size of fragments used in methods of the invention does not matter." The data reported in the Declaration, for example, at paragraphs 9, 10, 11, 13, 14, and 15, show that the methods described in the specification screen for any type of cancer in any bodily excretion or body fluid sample and demonstrate that a positive screen for cancer or precancer can be established by screening for the presence of at least a nucleic acid characteristic of cancer or precancer. Accordingly, performing the methods as claimed in the present application requires no undue experimentation, but only requires one of skill in the art to follow the outline provided in Applicant's specification. Therefore, Applicant submits that the specification as filed fully enables claims 7-14.

Rejection for Double Patenting

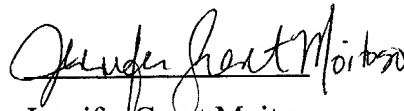
Claims 7-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of U.S. Patent Application No. 09/514,865 and are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-15 of issued U.S. Patent No. 6,586,177. Without acquiescing to the rejections, Applicant submits herewith a Terminal Disclaimer over U.S. Patent Application No. 09/514,865 and over issued U.S. Patent No. 6,586,177, and respectfully requests that the obviousness-type double patenting rejections be withdrawn.

CONCLUSION

Upon entry of this Response, Applicant respectfully requests reconsideration and withdrawal of the rejections, and submits that claims 7-14 are in condition for allowance. If the Examiner believes that a telephone conversation would expedite prosecution of this application, the Examiner is invited to call the undersigned attorney of record.

Respectfully submitted,

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Jennifer Grant Moitoso
Registration No. 51,752
Attorney for Applicants
TESTA, HURWITZ, & THIBEAULT, LLP
High Street Tower
125 High Street
Boston, MA 02110

Tel.: (617) 310-8423
Fax.: (617) 248-7100